EXHIBIT M

BUTLER | SNOW

March 7, 2013

Thomas P. Cartmell
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, Missouri 64112

RE: *In re: Ethicon, Inc. Pelvic Repair System*, Products Liability Litigation, MDL No. 2327

Dear Tom:

This letter is in response to your e-mail last night, March 6, 2013. In order to make the discussion easier to follow, I have reprinted some of your e-mail below.

First, let me start by saying that our primary goal at this point is to begin depositions in this case. You have requested that we provide you with dates for 44 witnesses, you have noticed multiple 30(b)(6) topics, and we will have a plethora of fact witness depositions to start as soon as the discovery pool is selected. In order for this discovery to be completed, we've got to get moving. I believe that a lot of the disputes we are having right now are "disputes in the abstract", in which plaintiffs and the defense are both trying to make sure they are not waiving any rights. I think that once we get started on these depositions that these fights in the abstract will greatly diminish as we all move forward to the mutual goal of complying with a tight scheduling order.

Second, in your e-mail you state that "it was pretty clear from our conversation yesterday, that you had not intended to bring any documents to the deposition or even respond to our requests." I think this fundamentally misconstrues our response and the fact that we are the party that reached out to you in the meet and confer, not vice-versa. We have already produced to you nearly 100 productions or supplemental productions. Although we are always willing to be helpful and in some cases have referenced specific documents by specific bates ranges, in general, we do not intend to reproduce to you the documents we have already produced to you. As you know, all of these productions and supplemental productions have been provided to you in the manner in which they were kept, in an electronic format that is equally searchable by you. But if you believe we should be doing something more specific to help you identify documents than we are already doing, please let us know and we will certainly consider it.

Third, as is more fully addressed below, I think a lot of the problem is caused by the multiple notices of deposition that have been provided to us and then superseded relating to the Design 30(b) and Regulatory Affairs 30(b) notices. In fact, we are still waiting on you to contact us to engage in additional meet and confer on the Design notice and to confirm that the Design Notice you informally provided to us are in fact the final notices that you intend to file (if they are).. As for the Revised Regulatory Affairs notice that you sent us on February 20, 2013, it

added an additional 12 document requests to the four that were included in the original notice. It has obviously taken some time to analyze the additional 12 requests, and only 22 calendar days elapsed between then and our response.

The six specific topics you listed in your e-mail were as follows:

> **1. We need you to agree to remove your objections to the topics for which you have designated Ms. Lin. I thought we had an agreement, but now you have simply objected to virtually every topic with vague objections. In fact, you have told us repeatedly that Ms. Lin will testify to various topics and, now, less than a week before her deposition, you have objected to the same topics. We do not want to be in a position of moving forward and you later taking the position that we have waived our right to any of the testimony we have asked for. Either you remove the objection, or agree that we are not waiving any arguments we have that we are entitled to the requested testimony by going forward;**

RESPONSE TO POINT 1:

We think the notice is very broad and there are many portions of this notice that: (a) are drafted so that no corporate representative could ever truly respond, because of their breadth; and (b) even if some of the topics are in and of themselves proper, due to the way in which Ethicon is structured, the topic requires multiple witnesses to address. We've explained that in our calls and we think everyone is on the same page. But by the same token, we feel that we have to preserve our objections on these issues and we have tried to do so. We anticipate that you are going to find that Susan Lin is well prepared to go forward on the topics related to regulatory approval and believe that it is in the interest of all parties that this deposition go forward. What we have tried to do in our response to you is memorialize what Ms. Lin will (and will not) be able to address in that deposition.

> **2. We also need you to remove your objections to the document requests to the extent you are producing documents and an agreement that by going forward we are not somehow waiving our arguments that we are entitled to the other documents requested. Your last minute objections to all these document requests have put us in a bind. For example, you routinely object to the request for the information we are seeking, but then state that "without waiving your objections" you will provide a few things (i.e. some org charts, some SOPs, etc.). But, with these broad, overarching objections to nearly all the document requests, how can we be sure that you are providing all of the relevant org charts or the other documents you have chosen to produce, versus relying on your objection to prevent you from making a complete production?**

RESPONSE TO POINT 2:

First, our objections are not last minute. As addressed above, you provided us with a notice of deposition on January 24, 2013. However, the certificate of service accompanying this motion was never filed with the Court and the notice was then superseded by another notice that you served on us on February 20, 2013, and for which you did file the certificate of service with

the Court, and then filed the notice itself on February 21, 2013. These notices are not the same, in fact, as I note above, the document requests are vastly different and include 12 additional (and extremely broad) topics. I note that we have had similar issues with the design notice which has changed several times. As Donna explained in her letter yesterday, we are not complaining about the superseding notice, nor did we attempt to use that as a reason to not produce Ms. Lin for her deposition. But this has made it harder for us to prepare and respond to you and has put us in a "bind." Please note that we sent the responses and objections to you on March 6, 2013, which is far less than the 30 days that we have under the Rules to respond.

Second, you are well aware of the productions we have made in this case which now total over seven million pages. Those productions have included numerous regulatory affairs central sources and custodians. The central sources include regulatory affairs organizational charts, regulatory affairs SOPs (including the SOPs contained in Productions 36, 40, 55, 70 and 93 for which we provided the Bates numbers), Labeling Control Agile Database (Prod. 32), GGM LCA Archive Folder Groupshare (Prods. 6, 19, 70 and 90), Regulatory Affairs\RA-CAPA\EWHU Draft TFDD SharePoint (Prod. 32), Copy Review Paper Files (Prods. 3, 4, 7, 14, 22, 32, 39, 70 and 90) and accompanying indexes provided on February 3, 2012 and April 10, 2012 and again on March 6, 2013, Sales and Marketing\Lynn Hall\TVT Groupshare (Prod. 14), EWHU Regulatory SharePoint (Prods. 33 and 61), RDEWHU SharePoint (Prod. 90), Regulatory Affairs\522 Orders Group Share, (Prods 61 and 95), Regulatory Affairs Group Shares (Prod. 96), The custodial files that are regulatory in some respect and that have been produced are Dan Smith, Donna Taggert, Laura Vellucci, John Young, Daharini Amin, Lisette Caro-Rosado, Katie Cheng, Susie Chilcoat, Lynn Hall, Jason Hernandez, Piet Hinoul, Scott Jones, Aaron Kirkemo, Susan Lin, Linda Linton, Bryan Lisa, Brian Luscombe, Kevin Mahar, Jonathan Meek, Melissa Muguruza, Pat Napoda, Mary O'Connell, Robin Osman, Ken Pagel, Paul Parisi, Bart Pattyson, David Robinson, Martin Weisberg, Axel Arnaud, Lisette Caro-Rosado, Judi Gauld, Evelyn Hall, Matt Henderson, Jason Hernandez, Joseph Herron, Marianne Kaminski, Tom Affeld, Laura Angelini, Catherine Beath, Lesley Fronio, Judi Gauld, Brian Kanerviko, Martin Madden, Iris Magalhaes, Pat Napoda, Lucy Paterson, Kelly Arnold, Boris Batlke, Scott Ciarrocca, Melissa Day, Paul DeCosta, James Flint, Kevin Frost, Dimpy Gupta, Matt Johnson, Dan Lamont, Brian Luscombe, Iris Magalhaes, David Overaker, Jennifer Paradise, Adrian Roji, Elizabeth Vailhe, Laura Vellucci, Frank Yasunas, and Vincenza Zaddem.

Finally, we think our response makes it clear to you the specific breakdown of the requests for which we are refusing to produce documents and the requests for which we are relying on our prior productions. Put differently, we have told you in each response whether we are or are not producing documents. The only document request for which we have not explicitly said that we will produce responsive documents is request number 16 which is as follows:

> **Document Request No. 16:** All documents that relate to U.S. and foreign regulatory affairs and matters concerning Ethicon, Inc.'s TVT products, including but not limited to regulatory communications, interchanges between Ethicon, Inc.'s personnel and any regulatory body or personnel, memoranda, electronic data, working drafts, regulatory guidance documents, internal writings, communications to and from Ethicon, Inc.

personnel regarding regulatory matters, labeling records, drafts of labeling records, minutes of meetings with regulatory personnel, regulatory contact reports or sheets, Investigational device submissions, 510(k) submissions, Safety Update Reports, and any and all other documents which in any way relate to regulatory affairs applicable to your TVT products from the date Ethicon, Inc. first started developing TVT until the present.

Responses and Objections to Document Request No. 16: Defendants object that this request is vague and ambiguous. In particular, various terms and phrases, including "internal writings," "communications to and from Ethicon, Inc. personnel," "labeling records," and "regulatory communications," are vague and ambiguous.
Defendants further object that the information sought in this request is more readily available to Plaintiffs from other sources. "Regulatory guidance documents," for example, are readily available on the FDA's website. Moreover, the regulatory documents for each of the devices have been produced in the manner they are kept in the ordinary course of business in an electronically searchable format and thus, this information is equally available to the Plaintiffs. These documents have been extensively enumerated above in the responses to document requests 1-15.
Finally, Defendants object that this request is overbroad and unduly burdensome. The devices are sold in, and hence subject to the governing regulations of, fifty-five countries or regions across the world. Those foreign jurisdictions have regulations and regulatory processes that bear no relationship to any of the surgeries at issue for any of the Plaintiffs. Defendants invite Plaintiffs to meet and confer to determine whether this request can be narrowed.

I think that you will agree with me that this topic is extraordinarily broad and it is impossible to determine what would and would not be responsive. We have explicitly invited you to meet and confer on this issue so that hopefully you will agree to narrow it into something that is manageable and/or prioritize what you seek.

3. **With respect to document request 6, we cannot agree that you should only produce a handful of regulatory SOPs, and only the current version. We would like the regulatory SOPs during the life of these products. Clearly, because Ms. Lin is designated to talk about the regulatory clearance process for the products, interactions with the FDA about the products, the corporate structure and organization of the regulatory affairs department, the companies policies and procedures related to labeling regulations (including adverse reactions and contraindications), and 510(k) compliance, submission, preparation, decision making or any other issues related to 510(k) compliance or submission, the company SOPs related to those topics should be produced or bates ranges provided for those SOPs. A possible compromise would be that if you have an index or indexes of SOPs for the regulatory department, we will go through it and tell you what we want. However, we will want the policies from the relevant time period. We obviously cannot agree to simply allow your witnesses to tell us that they don't know whether the SOPs you produced were in effect at relevant times. There might be**

another compromise that I'm not thinking about, but if you can only provide the current policies, we need to take this up with the Court;

RESPONSE TO POINT 3:

We are willing to work with you on some compromise on this point. The complicating factor here is that for some of these products have an extensive product life span so assembling all SOPs that were in existence during the life span of that product may, in some case, be a very burdensome task. As set forth in Donna's letter yesterday, we have previously produced numerous SOPs related to regulatory affairs (which were identified by bates range) and we have also given you the current version of the Regulatory Affairs SOPs that Ms. Lin commonly uses. Perhaps you could take a quick look at what has already been produced and let me know if there is a specific SOP for which you feel you need all the prior versions? Another potential compromise might be for us to obtain revision histories for specific SOPs. I look forward to discussing this matter further.

4. We asked you to produce bates ranges for the document requests, but your responses rarely provide that information. Rather, you have typically only identified custodial files that you say contain responsive documents. We are willing to go forward with Ms. Lin's deposition, but we want to be clear that we are not waiving our right to seek Court intervention to obtain more specific responses in accordance with the Federal Rules of Civil Procedure and we would like you to agree;

RESPONSE TO POINT 4:

I'm not sure exactly what you are asking. If you are asking whether we agree that if you take Susan Lin's deposition that at later point: (a) you can litigate in the abstract the issue of whether we have to provide bates ranges to you in our document responses; or (b) that you can litigate whether we need to provide bates ranges to you in response to the document request that accompanied the February 20, 2013, notice, yes, we agree that you are not waiving this right by taking Ms. Lin's deposition prior to obtaining court resolution of this issue. However, I want to be clear that we don't necessarily agree that another deposition will be necessary. I did not read your e-mail to suggest that, I just wanted to make sure we are all on the same page on that issue.

As we have stated to you several times, the documents that have been produced are in searchable format. We have provided you with the custodial and central sources. Pursuant to Fed. R. Civ. P. 33(d), we have specified the records in sufficient detail to allow you to locate and identify them as readily as we could.

5. With respect to the 510k submissions, we do not believe that you have provided us with the actual submissions. For example, the bates range you provided for the TVT-Secur 510k submission is obviously not Ethicon's submission because it has correspondence from the FDA included. It also includes a freedom of information bates # on the pages. We have not yet been through all of the bates ranges you provided, but to the extent you did not provide the actual 510k submission for any of the products, please do so; and

RESPONSE TO POINT 5:

Just because this is a copy from a FOIA copy doesn't mean it isn't our submission, but we are glad to provide you with the Bates numbers of the original submission. The Bates numbers are ETH.MESH 00019925-00020019.

6. With respect to Ms. Lin's personnel file, we would like you to agree that you will supplement the production of her personnel file with her compensation information as soon as it is available.

RESPONSE TO POINT 6:

We will review the compensation information once it is available next week and let you know our position as soon as possible.

Sincerely,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC

/s/ Benjamin M. Watson

Benjamin M. Watson

BMW:fsw

cc: Donna B. Jacobs
Phil Combs
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